IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Roanoke Division

MARY SHARON WALKER, Plaintiff, v. NEW ENGLAND COMPOUNDING PHARMACY, INC. d/b/a NEW ENGLAND COMPOUNDING CENTER, and IMAGE GUIDED PAIN MANAGEMENT, P.C. d/b/a INSIGHT IMAGING ROANOKE, Defendants.	)	Civil Action No. 7:12-cv-564

REPLY IN SUPPORT OF MOTION TO DISMISS FOR
FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

COMES NOW Defendant Image Guided Pain Management, P.C., d/b/a Insight Imaging–Roanoke ("IGPM"), by counsel, and for its Reply in Support of Motion to Dismiss Plaintiff's Complaint, states:

I. Plaintiff incorrectly makes a fraudulent joinder argument in response to IGPM's 12(b)(6) motion.

The lone Virginia case to which Plaintiff cites in opposition to IGPM's argument that it cannot be liable under a products liability theory[1] is *Sanders v. Medtronic, Inc.*,

[1] At the end of her Brief in Opposition, Plaintiff contends that IGPM's Motion to Dismiss does not address Plaintiff's implied warranty claims. This is incorrect. The analysis in IGPM's 12(b)(6) memorandum concerning the distinction between a seller and a service provider is directly applicable to the implied warranty claims as well as the products liability claims. In the second paragraph of IGPM's argument section in its brief, IGPM states that, "[i]n order to establish warranty claims against IGPM, Plaintiff must be able to show that IGPM is a seller of goods under the U.C.C." (IGPM's Br. Supp. p.3; *citing* Va. Code. § 8.2-313–15.) If IGPM is engaged in the provision of health care services, then plaintiff's claims for products liability *and* implied warranty cannot stand.

2006 U.S. Dist. LEXIS 45516 (E.D. Va. 2006). That opinion examined whether a defendant health care provider was fraudulently joined in a products liability case for the sole purpose of defeating diversity jurisdiction. *Sanders*, U.S. Dist. LEXIS 45516 at *20–21. The fraudulent joinder standard of review is more lenient than the standard of review for a 12(b)(6) motion: "The party alleging fraudulent joinder bears a heavy burden—it must show that the plaintiff cannot establish a claim even after resolving all issues of law and fact in the plaintiff's favor. **This standard is even more favorable to the plaintiff than the standard for ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6)**" *Hartley v. CSX Transp., Inc.*, 187 F.3d 422, 424 (4th Cir. 1999) (emphasis added); *citing Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 852 (3d Cir. 1992) (Inquiry into validity of complaint is **more searching** under Rule 12(b)(6) than when party claims fraudulent joinder).

This Court recently recognized the difference between the two standards in *Walters v. Holiday Motor Corp*, Case No. 7:12-cv-11, 2012 WL 5465012 (W.D. Va. May 21, 2012). There, Judge Turk observed that "[t]he inquiry into fraudulent joinder is . . . more favorable to the plaintiff than the standard used to evaluate motions to dismiss under Fed. R. Civ. P. 12(b)(6). *Walters*, 2012 WL 5465012 at *1. To prevail on a fraudulent joinder motion, the defendant must "negate all possibility of recovery . . . [i]f a court finds even a 'slight possibility of a right to relief' or a 'glimmer of hope' for the plaintiff" the motion must fail. *Id.* Thus, the *Sanders* Court's conclusion that the defendant health care provider was not fraudulently joined is in no way preclusive of IGPM's 12(b)(6) motion.

Moreover, the *Sanders* opinion is a narrow holding. It stands only for the following proposition: because the Supreme Court of Virginia has not ruled on the issue of whether health care providers can be subject to a products liability claim—even though Virginia's trial courts have held that they cannot—then the "glimmer of hope" for liability exists such that the case required remand. *Sanders*, U.S. Dist. LEXIS 45516 at *20–21. When analyzed under the standard of review for a 12(b)(6) motion, however, that "glimmer of hope" does not suffice to save plaintiff's claim. As discussed in IGPM's initial memorandum, the majority rule across the nation precludes the relief plaintiff seeks, Virginia's trial courts have rejected plaintiff's claims and the Supreme Court of Virginia, in *Commonwealth of Virginia Dept. of Taxation v. Bluefield Sanitarium, Inc.*, 216 Va. 686, 689, 222 S.E.2d 526, 528 (1976), expressly classified a health care provider as a service provider, not a seller of goods. "No taxable event occurs with respect to drugs supplied by the hospital to the patient, for such drugs are being supplied and administered in the performance of its **service** as a hospital . . . the hospital is the '**consumer**' in the tax sense because all property acquired by it is for use in the performance of its **service** to patients." *Id.* (emphasis added).

II. Holding health care providers liable under a products liability theory is bad public policy.

Plaintiff's citation to a 40 year-old Supreme Court of Illinois opinion is illustrative of the public policy concerns, discussed at length in IGPM's initial brief, with holding health care providers liable under a products liability theory. In *Cunningham v. MacNeal Memorial Hosp.*, 47 Ill. 2d 443 (Ill. 1970), the court held a hospital strictly liable under a products liability theory for a tainted blood transfusion. *Cunningham*, 47 Ill. 2d at 450–51. In response to the *Cunningham* decision, the Illinois General Assembly

immediately enacted the Blood and Organ Transaction Liability Act, 745 ILCS § 40/1 et seq. That Act prohibits strict liability or warranty claims regarding the "procuring, furnishing, donating, processing, distributing or using" human blood products or tissue "for the purpose of injecting, transfusing or transplanting" them into the human body. In that Act's "Declaration of Public Policy," the General Assembly codified its conclusion that the liability imposed in *Cunningham* is bad public policy:

> The imposition of legal liability without fault upon the persons and organizations engaged in such scientific procedures **inhibits the exercise of sound medical judgment** and restricts the availability of important scientific knowledge, skills and materials. It is therefore the public policy of this State to **promote the health and welfare of the people by limiting the legal liability** arising out of such scientific procedures **to instances of negligence or willful misconduct.**

745 ILCS § 40/1 (emphasis added).

Plaintiff's citation to a non-binding Illinois decision that was superseded by statute underscores IGPM's argument that allowing Plaintiff's claims to proceed would inhibit the safe and effective administration of medical services. As discussed at length in IGPM's initial brief, many jurisdictions have found that imposition of products liability on a health care providers would "'place an unrealistic burden on the physicians and hospitals of this state to test or guarantee the tens of thousands of products used in hospitals by doctors.'" *Royer v. Catholic Medical Center*, 144 N.H. 330, 335, 741 A.2d 74, 78 (1999) (citing *Ayyash v. Henry Ford Health Sys.*, 533 N.W.2d 353, 356 (Mich.App 1995); *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1110 (N.M. 1996). Additionally, "research and innovation in medical equipment and treatment would be inhibited" if products liability actions could be maintained against the service provider. *Id.* (citing

Cafazzo v. Cent. Medical Health Servs., 668 A.2d 521, 527 (Pa. 1995); *Hoff v. Zimmer, Inc.*, 746 F.Supp. 872, 874–75 (W.D. Wis. 1990)). As Plaintiff's own case law and the opinions of many other jurisdictions make clear, the relief Plaintiff seeks has the potential to cause severe disruptions to the health care system. This Court should resist imposing that burden.

III. Virginia's Medical Malpractice Act applies to plaintiff's claims.

Plaintiff's argument that her claims do not concern "health care" is belied by the express allegations of her Complaint. Plaintiff states, "[t]his case seeks redress for *Defendants' sale and injection*" of the methylprednisolone acetate at issue. (Compl. ¶ 8.) Plaintiff claims that she "received [the] injections of NECC's contaminated steroid . . . at Insight Imaging located in Roanoke, Virginia." (Compl. ¶ 20.) Plaintiff claims that the *injection* "caused Plaintiff bodily harm, emotional distress, other personal injuries, and to incur medical and other expenses." (Comp. ¶ 20.) Under the language of her Complaint, Plaintiff cannot credibly argue that her claims do not concern health care.

Even if the injection of the steroid were not pleaded as an essential causal component of Plaintiff's damages, Plaintiff's allegations of negligence implicate Virginia's Medical Malpractice Act ("the Act"). Plaintiff cites to *Alcoy v. Valley Nursing Homes, Inc.*, 272 Va. 37, 630 S.E.2d 301 (2006), but that case is not apposite to the case at bar. There, the Supreme Court of Virginia observed that the defendant's status as a nursing home presented unique considerations:

> [T]he factual context of a tort alleged to have occurred in a nursing home facility presents certain unique circumstances for our consideration. . . . [A] nursing facility . . . engages in many professional services related to patient care that **do not occur during the course of a medical procedure or treatment designed to address a particular medical**

> **condition.** Thus, the provision of health care and professional services at facilities of this nature may, depending on the particular facts of a case, include additional services **beyond those traditionally rendered in a medical office** or hospital setting.

Alcoy., 272 Va. at 42-43, 630 S.E.2d at 303–04. Unlike *Alcoy*, the present case involves "professional services related to patient care" that *did* occur as part of "treatment designed to address a particular medical condition." *Id.* That treatment was part of the services "traditionally rendered in a medical office or hospital setting." *Id.* at 304.

When the alleged negligence occurs during the rendering of health care by a health care provider, the substance of the claim is medical malpractice. *Gonzalez v. Fairfax Hosp. Sys., Inc.*, 239 Va. 307, 310 389 S.E.2d 458, 459 (1990). Gonzalez claimed that his action was for ordinary negligence, and not medical malpractice. The Supreme Court of Virginia stated that the language of the Medical Malpractice Act is clear and unambiguous and applied the definitions of "malpractice," "health care," and "health care provider." The Court held that the action was a medical malpractice action because all of the definitions applied to the alleged facts.

By way of comparison, a pharmacist engaged in the process of filling a prescription is a health care provider engaged in medical services subject to the Medical Malpractice Act. *See* Va. Code § 8.01-581.1 (including "pharmacist" under the definition of "Health care provider"). A pharmacist's act of dispensing a drug to a patient is likewise subject to the Act. *See Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397, 405 (1988) ("Only a tortured construction of the Medical Malpractice Act would include within its provisions all of the acts performed by pharmacists except the ultimate act to which all others are merely preparatory.") Therefore, the Act includes within its provisions a pharmacist's preparation and delivery of drugs. To parrot the

Gressman court, only a tortured reading of the Act would include within its provisions all of a physician's actions in diagnosing a patient and prescribing treatment, but exclude from its provision the physician's prescription and procurement of medicine. Plaintiff seeks to cut an arbitrary hole in the coverage of the Act simply to avoid the pre-suit certification requirement. This Court should require the Plaintiff to undergo Virginia's minimally burdensome certification process rather than issue a decision that would exclude one action in a chain of events that are otherwise covered under the Act.

IV. The Virginia Legislature vests responsibility for sterile medicine with pharmacists.

Plaintiff's argument in response to IGPM's observation that the Virginia Code vests "final" responsibility for ensuring a drug's sterility with pharmacists under Code § 54.1-3410.2, is to ask this Court to simply ignore that code provision. Plaintiff is arguing that a common-law duty should be imposed on a physician even though the legislature has placed sole responsibility for that duty with a different entity. The Virginia Legislature vested pharmacists with the responsibility for supervising the compounding process, "which shall include a **final** check for accuracy and conformity to the formula of the product" and for "ensur[ing] compliance with USP-NF standards for . . . sterile . . . compounding." Va. Code § 54.1-3410.2(D), (E). Plaintiff contends that IGPM has produced no authority for the proposition that it cannot be liable for negligence due to the existence of the these code provisions, but this is an incorrect statement of the parties relative burdens. On a motion to dismiss, once the defendant has shown that plaintiff's claim runs afoul of the Virginia Code, it is the *plaintiff's* burden to demonstrate that the Court should nonetheless impose a common-law duty where the Legislature chose not to

place a statutory duty. It is, therefore, *Plaintiff's* dearth of authority on this point which is telling.

Plaintiff also claims that the burden she seeks to impose is minimal. She claims that it is merely a "common-law duty to use reasonable care in the purchase of its medications." She claims further that there are many suppliers of methylprednisolone acetate, "such as Pfizer," that manufacture that drug and could have supplied it for plaintiff's treatment. But this burden (which the Legislature chose not to impose on physicians) is entirely undefined and, despite Plaintiff's protestations otherwise, would be incredibly onerous. How is any physician supposed to exercise reasonable care in choosing its pharmacist without a corresponding duty to inspect the pharmacy? How would IGPM know the particular conditions at a particular compounding facility on any given day, without inspecting the site? The only answer is that IGPM would have to rely on the assurances of a third party, because physicians could not take time to tour the country and inspect compounding facilities without major disruptions to their practice. The Virginia Legislature chose that third party: pharmacists, pursuant to Code § 54.1-3410.2(D). Plaintiff's insistence that the Legislature's decision bears no weight is unfounded and wrong.

V. Plaintiff's express warranty claim is inadequately pleaded.

Conclusory allegations concerning the existence of an express warranty that only set forth a legal basis for its creation are insufficient under Virginia law. *Pulte Home Corp. v. Parex, Inc.*, 256 Va. 518, 523–24, 579 S.E.2d 188, 190–91 (2003). In *Pulte*, a cross-claiming defendant argued that its approval of the use of a defective product was based on the express warranty of its co-defendant that the product was durable and water-

resistant. *Id.* at 522–23, 579 S.E.2d at 190. The defendant making the cross-claim pleaded that its co-defendant warranted the product "by way of affirmations of fact, promises, descriptions, and/or use of samples and/or models regarding the appearance, durability, and/or water-resistance of [the product]." *Id.* at 532, 579 S.E.2d at 190. Noting that this "allegation merely parroted the language of Code § 8.2-313, which sets forth several *legal* bases for the creation of express warranties," the Court concluded that the allegation "amounted to no more than a legal conclusion."[2] Accordingly, the Supreme Court of Virginia upheld the demurrer. *Id.* The same analysis holds here. Plaintiff's one-sentence assertion that an express warranty existed is conclusory and insufficient. It provides less detail than the claim in *Pulte* and, consequently, it should be dismissed.

CONCLUSION

WHEREFORE, Defendant Image Guided Pain Management, P.C. d/b/a Insight Imaging Roanoke, respectfully moves this Court to Grant its Motion to Dismiss for the reasons stated above and for the reasons stated in its Memorandum in Support of Motion to Dismiss, to enter final judgment in its favor, to dismiss this action against it from the Court's docket, to award it the costs and attorneys' fees associated with the defense of this action, and for such other and further relief as the needs of this case may require and which this Court deems appropriate.

[2] The co-defendant subject to the warranty claim in *Pulte* craved oyer for documents supporting the express warranty claim and none were produced.

Respectfully submitted,

IMAGE GUIDED PAIN MANAGEMENT, P.C.

By: /s/ Michael P. Gardner

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 20th day of March 2013, a true and exact copy of the foregoing was filed with the Clerk of the Court using the CM/ECF filing system, thereby providing electronic notice to jtravers@millerfirmllc.com, mmiller@millerfirmllc.com, and will@moodyrrlaw.com, counsel for plaintiff, and to rebecca.herbig@bowmanandbrooke.com, counsel for defendant NECC.

/s/ Michael P. Gardner